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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,058	10/24/2005	Hubert Lochard	3493-0149PUS1	8305

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EXAMINER	
VU, JAKE MINH	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
01/14/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/554,058	LOCHARD ET AL.	
	Examiner	Art Unit	
	Jake M. Vu	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *11 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12-14 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment filed on 11/04/2009.

- Claims 1, 3, 5-6, 8-11, 15 have been amended.
- Claim 16 has been added.
- Claims 1-16 are pending in the instant application.
- Claims 11 and 15 have been previously withdrawn from consideration.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10, 12-14, 16 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over copending Application

No. 10/594,740 and 10/492,346 **are maintained** for reasons of record in the previous office action filed on 08/04/2009 and as discussed below.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 16 recites the newly amended limitation of "wherein step (a) is conducted in the absence of carbon dioxide"; however, the specification as-filed does not provide a written description or set forth the metes and bounds of this phrase. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, introduce new concepts and thus violate the written description requirement of the first paragraph of 35 U.S.C. §112.

Applicant is required to cancel the new matter in the response to this Office action. Alternatively, Applicant is invited to identify sufficient written support in the original specification for the "limitations" indicated above.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 14 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, pertaining to "by mass" **are withdrawn** in view of Applicant's amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 10, 12, 13 rejected under 35 U.S.C. 102(b) as being anticipated by FREISS et al (WO 03/030867) **are maintained** for reasons or record in the previous office action and discussed below in better detail using the translation provided by Applicant on 11/04/2009.

Applicant's claims are directed to a method of making a molecular complex comprising of: bringing an active substance, such as tiaprofenic acid, into contact with a host molecule, such as cyclodextrin; carrying out a molecular diffusion step by stirring/bringing a dense fluid under pressure, such as CO2, in the presence of a

diffusion agent, such as water; recovering the molecular complex formed. Additional limitations include: pressure is between 5MPa and 40MPa; temperature is between 0 and 120ºC;

FREISS teaches a method of making a molecular complex comprising of: bringing an active substance, such as anilide derivative (see pg. 10, line 19) or piroxicam (see pg. 7, line 12), which is an anti-inflammation agent, into contact with a host molecule, such as β-cyclodextrin or γ-cyclodextrin (see pg. 7, line 13; pg. 12, line 5 and line 36-37), wherein the mixture of active substance and cyclodextrin can be done prior to contact with the supercritical fluid (see pg. 12, line 35—pg. 13, line 2), which is carbon dioxide; carrying out a molecular diffusion step (see pg. 10, line 15-30, especially line 22) by stirring/bringing (see pg. 15, line 26-28),a dense fluid under pressure, such as CO2 (see pg. 10, line 22-23; pg. 12, line 8-11), in the presence of a diffusion agent, such as water (see pg. 10, line 22; pg. 15, line 29-37); washing the interaction compound with flow of supercritical fluid (see pg. 10, line 27-28); recovering the particles (see pg. 10, line 29), which reads on molecular complex formed. Additional disclosures include: pressure is between 5MPa and 40MPa (see pg. 16, line 11); temperature is between 0 and 120ºC (see pg. 16, line 12); these steps can be carried out in batch or uninterrupted (see pg. 10, line 4-5); steps that do not involve the active substance used was generated by supercritical was known in the prior art (see pg. 7, line 5-26).

Note, during the search of the elected species, some non-elected species were found in the search; this is not indicative that a through search of all the species have been done.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10, 12-14, 16 rejected under 35 U.S.C. 103(a) as being unpatentable over FREISS et al (WO 03/030867) in view of CHOWDHARY et al (US 6,693,093) **are maintained** for reasons or record in the previous office action and discussed below in better detail using the translation provided by Applicant on 11/04/2009.

As discussed above, FREISS teaches a method of making a molecular complex comprising of: bringing an active substance, such as anilide derivative (see pg. 10, line 19) or piroxicam (see pg. 7, line 12), which is an anti-inflammation agent, into contact with a host molecule, such as β-cyclodextrin or γ-cyclodextrin (see pg. 7, line 13; pg. 12, line 5 and line 36-37), wherein the mixture of active substance and cyclodextrin can be mixed prior to contact with the supercritical fluid (see pg. 12, line 35—pg. 13, line 2), which is carbon dioxide; carrying out a molecular diffusion step (see pg. 10, line 15-30, especially line 22) by stirring/bringing (see pg. 15, line 26-28),a dense fluid under pressure, such as CO2 (see pg. 10, line 22-23; pg. 12, line 8-11), in the presence of a

diffusion agent, such as water (see pg. 10, line 22; pg. 15, line 29-37); washing the interaction compound with flow of supercritical fluid (see pg. 10, line 27-28); recovering the particles (see pg. 10, line 29), which reads on molecular complex formed. Additional disclosures include: pressure is between 5MPa and 40MPa (see pg. 16, line 11); temperature is between 0 and 120ºC (see pg. 16, line 12); these steps can be carried out in batch or uninterrupted (see pg. 10, line 4-5); steps that do not involve the active substance used was generated by supercritical was known in the prior art (see pg. 7, line 5-26).

FREISS does not specifically teach using an active substance, such as tiaprofenic acid.

CHOWDHARY teaches nonsteroidal anti-inflammatory drugs include piroxicam and tiaprofenic acid (see col. 11, line 33-44).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate tiaprofenic acid into FREISS's method. The person of ordinary skill in the art would have been motivated to make those modifications, because and reasonably would have expected success because tiaprofenic acid and piroxicam are functional equivalents of nonsteroidal anti-inflammatory drugs.

The references do not specifically teach adding the ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It

would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

Response to Arguments

Applicant argues that taking into account the enclosed more accurate English translation of Freiss '867, it is submitted that Freiss '867 discloses a process wherein the described anilide derivative is first generated by supercritical CO2 and therefore is no longer poorly soluble in an aqueous medium when it is brought into contact with the host molecue. The Examiner finds this argument unpersuasive, because as discussed above, FREISS also teaches the mixture of active substance, such as anilide derivative, and cyclodextrin can be mixed prior to contact with the supercritical fluid (see pg. 12, line 35—pg. 13, line 2), which is the same steps as claimed by Applicant; thus, is poorly soluble in aqueous medium.

Applicant argues that a further step is required in addition to step (c) of the method of the present invention, which is a washing step with supercritical CO2. This step is not present in the claimed method of the present application. The Examiner finds this argument unpersuasive, because FREISS teaches this step at pg. 10, line 27-28).

Applicant argues that the method of the present invention is less costly and shorter while allowing the complexation of active substances poorly soluble in an

aqueous medium in order to increase their solubility. Freiss '867 fails to disclose or suggest that it is possible to simplify the process described therein while maintaining advantageously high inclusion rates as evidenced by the examples described in the present specification discussed above. Rather, the preliminary step involving the supercritical CO2 and the last washing step of Freiss '867 are described as being essential steps in order to increase the solubility of the anilide derivative. The Examiner finds this argument unpersuasive, because FREISS teaches steps that do not involve the active substance used was generated by supercritical was known (see pg. 7, line 6-25).

Applicant argues that the method of the present invention requires the presence of a diffusion agent which is added to the mixture of the active substance and host molecules. The Examiner finds this argument unpersuasive, because as discussed above, FREISS teaches using diffusion agents, such as water.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618